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(71) Applicant: BIODAN MEDICAL SYSTEMS LTD  
Kiryat Weizmann  
Rehovot 76120(IL)

(72) Inventor: Eshel, Uzi  
28 Ahi-Dakar Street  
Herzlia(IL)

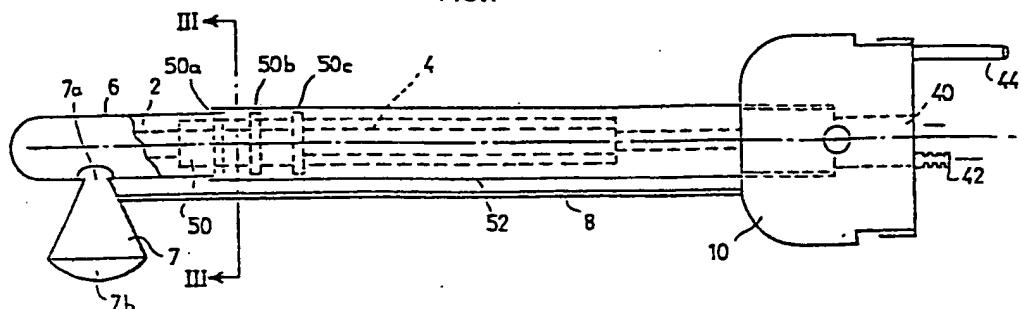
(72) Inventor: Lev, Avigdor  
12 Mordechai Hefetz Street  
Petach Tikva(IL)

(74) Representative: Schmitz, Jean-Marie et al,  
OFFICE DENNEMEYER S.à.r.l. P.O. Box 1502  
L-1015 Luxembourg(LU)

(54) Applicator for insertion into a body opening for medical purposes.

(57) An applicator for insertion into a body opening for medical treatment or for diagnostic purposes comprises an elongated jacket (2) for insertion into the body opening, a disposable sleeve (6) received on the jacket (2), and a balloon (7) integrally formed on the disposable sleeve (6) at one side of the jacket (2). The balloon (7) is inflatable by a fluid to press the opposite side of the jacket (2) and sleeve (6) laterally against the tissue of the body opening, thereby to fix the position of the jacket (2) within the body opening and to conform the pressed body tissue to the shape of the opposite side of the jacket (2).

FIG.1



APPLICATOR FOR INSERTION INTO A BODY OPENING  
FOR MEDICAL PURPOSES

The present invention relates to an applicator adapted to be inserted into a body opening for various medical purposes, e.g. for medical treatment or medical diagnosis. The invention is particularly useful as a heating applicator for insertion through the anus into the rectum of a patient for use in hyperthermia treatments, and is therefore described below with respect to this application.

10 The applicator of the present invention is particularly useful with the catheter and probe described in our Israel Application No. 78756 filed the same date as this Application.

Hyperthermia is a recognized technique for rendering certain therapeutic treatments to a patient by the application of heat to the portion of the patient's body to be treated. A large number of applicators have been developed for treating cancer, or for other therapeutic purposes such as the treatment of hemorrhoids, as described for example in USA Patents 4,375,220, 4,312,364, 4,311,154, 4,227,535, 4,186,729, 4,154,246, 4,140,130, 4,016,886, 2,043,083, 2,032,859 and 1,433,286.

An object of the present invention is to provide an applicator for insertion into a body opening for purposes of performing a medical treatment or a medical diagnosis.

According to the present invention, there is provided an applicator for insertion into a body opening for medical treatment or for diagnostic purposes, characterized in that the applicator

includes: an elongated jacket for insertion into the body opening; a disposable sleeve received on said jacket; and a balloon integrally formed on said disposable sleeve at one side of said jacket, which 5 balloon is inflatable by a fluid to press the opposite side of the jacket and sleeve laterally against the tissue of the body opening, thereby to fix the position of the jacket within the body opening and to conform the pressed body tissue to the shape of said 10 opposite side of the jacket.

The invention is particularly useful for rendering hyperthermia treatments. For such an application, the applicator further includes a microwave antenna disposed within the jacket, the 15 jacket further including cooling ducts adjacent its outer surface for circulating a cooling fluid therethrough in order to prevent undue heating of the body tissue in direct contact therewith. The balloon, when inflated, thereby also effects efficient cooling 20 of the body tissue in contact with the opposite side of the jacket. The applicator may thus be used for heating tissue directly in contact with the outer face of the applicator, in which case a cooling fluid would not be circulated through the cooling ducts; 25 alternatively, the applicator may be used for heating more remotely-located tissue, in which case a cooling fluid would be circulated through the cooling ducts in order to prevent undue heating of the tissue in direct contact with the applicator.

30 The invention is herein described, by way of example only, with reference to the accompanying drawings, wherein:

Fig. 1 is a side elevational view illustrating one form of heating applicator

constructed in accordance with the present invention, the sleeve and balloon carried by the applicator being shown in its inflated condition;

Fig. 2 is a longitudinal sectional view of  
5 the applicator of Fig. 1 with the heating element and  
balloon-sleeve removed;

Fig. 3 is a transverse sectional view along  
lines III--III of Fig. 1;

Fig. 4 is a diagrammatic view illustrating  
10 the formation of the channels in the outer face of the  
inner sleeve, which channels cooperate with the outer  
sleeve of the jacket to define the cooling ducts;

Fig. 5 is an end view, partly in section, of  
the end fitting in the applicator of Fig. 1;

15 Figs. 5a, 5b and 5c are sectional views  
along lines a--a, b--b, c--c, respectively, of Fig.  
5;

and Fig. 6 is a sectional view of the  
microwave antenna used as the heating element in the  
20 applicator of Fig. 1.

The applicator illustrated in the drawings  
comprises an elongated jacket, generally designated 2,  
for insertion into a body cavity at the location of  
the tissue to be heated. The applicator illustrated  
25 in Fig. 1 is particularly designed for insertion via  
the body anus into the rectum for treating this  
region of the body, although it will be appreciated  
that the invention could be applied to other body  
cavities and used for other therapeutic treatments or  
30 for diagnostic purposes.

The illustrated applicator includes a  
heating element in the form of a microwave antenna,  
indicated by broken lines 4 in Fig. 1 but more  
particularly illustrated in Fig. 6, generating RF

electromagnetic radiation for heating the body tissue. The applicator further includes a disposable sleeve 6, carried by the jacket 2 and integrably formed with a balloon 7 projecting laterally at the distal end of 5 the sleeve. Balloon 7 is inflatable by air or water applied via a tubelet 8 extending through an end fitting 10 externally of the sleeve. The balloon 7 is of generally conical configuration when inflated, having a narrow tip 7a joined to the sleeve 6, and a 10 wide base 7b at its opposite end engageable with the body tissue at one side of the body opening when the balloon is inflated while the applicator is within the body opening.

Antenna 4 is more particularly illustrated 15 in Fig. 6. It is constructed of a coaxial cable including an inner electrical conductor 12 and an outer electrical conductor braid 13 separated from the inner conductor by a dielectric layer 14. The dielectric layer 14 is removed from the end of the 20 coaxial cable to bare the inner conductor 12, and the inner conductor is then covered by a dielectric layer 15, e.g. glass or ceramic having a dielectric constant of at least 2. The outer conductor braid at the end 25 of the cable is folded back over itself and is separated from the underlying braid by a dielectric layer 16. The outer face of the antenna is then covered by a protective coating 18, as by dipping in a bath of insulating material.

As shown more particularly in Figs. 2 and 3, 30 jacket 2 includes an inner, relatively thick core 20, an outer thin sleeve 22, and a solid tip 24 at the distal end of the applicator. Inner core 20 is formed with an axially-extending bore 26 for receiving the microwave antenna 4, and its outer face is formed

with a plurality of axially-extending ribs 20a to define a plurality of recessed channels 28, as more particularly illustrated in Figs. 3 and 4. Channels 28 form, with the outer sleeve 22, a plurality of cooling ducts for circulating a cooling fluid, such as water.

As shown in Fig. 4, the cooling ducts defined by recessed channels 28 extend the complete length of the jacket in a sinuous manner from the cooling fluid inlet 30 at the proximal end of the applicator (left end in Fig. 4, but right end in Figs. 1 and 2) back and forth with respect to the opposite, distal end of the applicator, the water exiting via the water outlet 32 at the proximal end of the applicator.

15       The solid tip 24 at the distal end of the applicator is formed with an annular recess 34 for receiving the distal ends of the inner core 20 and the outer sleeve 22. The proximal ends of these sleeves are received within a cylindrical recess 36 formed 20 centrally of the end fitting 10.

End fitting 10 is further formed with a central bore 40 for passing the microwave heating antenna 4 therethrough into the bore 26 of the inner core 20. Fitting 10 is further formed with a pair of 25 lateral bores 42, 44 (Figs. 5, 5a) communicating with the cooling ducts 28 for circulating the cooling fluid, (e.g., water) therethrough. Bore 42 is the inlet for the cooling water, and bore 44 is the outlet.

30       End fitting 10 is formed with a further bore 46 (Fig. 5, 5b) serving as the inlet for admitting air or water to inflate balloon 7 via tubelet 8 received within bore 46 and connected to the balloon. End fitting 10 includes a still further bore 48 (Figs. 5,

5c) for receiving the electrical leads of three thermocouples 50a, 50b, 50c (Fig. 1) which measure the temperature within the body opening into which the applicator has been inserted.

The inner core 20 is formed, for approximately one-half its circumference, with the ribs 20a defining the cooling ducts 28; for the other half of its circumference, the outer face of sleeve 22 is lined with a copper reflector layer 52, as shown in Fig. 3, extending substantially along the complete length of the sleeve, this being at the side of the jacket carrying the inflatable balloon 7. Copper layer 52 reflects the electromagnetic radiation generated by the microwave antenna 4 in the direction away from balloon 7 so that the generated heat is concentrated in the body tissue at the side of the body opening opposite to the balloon.

Thermocouples 50a, 50b, 50c (Fig. 1) are disposed substantially at the outer surface of jacket 2 adjacent to its distal end, and are spaced from each other a slight distance longitudinally of the jacket, as shown in Fig. 1, in order to measure the temperature at these three selected regions of the body cavity in which the applicator is inserted. The 25 electrical conductors to these thermocouples pass axially along the side of the jacket occupied by reflector 52, on the outer face of the reflector as shown at 54a in Fig. 3, to the axial location of the respective thermocouple, and then pass circumferentially along the outer face of the reflector to their respective thermocouple, as shown at 54b in Fig. 3. Reflector 52 thus substantially shields the electrical conductors from the electromagnetic field produced by the antenna.

An insulating layer 56 is applied to insulate electrical conductors 54a, 54b from the reflector 52, and also to insulate the thermocouples 50a-50c from the cooling effect produced by the 5 cooling fluid circulated through the cooling ducts 28. An outer thin protective layer, such as a dipped coating, is applied to the outer face of jacket 2 covering the thermocouples 50a-50c and their electrical conductors 54a, 54b.

10 The disposable sleeve 6, including the balloon 7 and tubelet 8, is supplied separately and may be applied to the outer face of the applicator 2 just before it is intended to be used. Sleeve 6 is preferably formed intergrally with balloon 7 from an 15 elastomer, e.g., rubber latex. For sanitary purposes, the sleeve is disposable for one-time use.

The manner of using the heating applicator illustrated in the drawings will be apparent from the above description. Thus, after a sleeve 6, with its 20 integrally formed balloon 7 has been applied to the applicator, the applicator is inserted into the body opening, for example into the rectum via the anus, while balloon 7 is deflated. When the distal end (left end) of the applicator is in proper position within 25 the body opening, balloon 7 is inflated by pressurized air or water applied via bore 46 in end fitting 10, and tubelet 8. The inflation of the balloon causes it to firmly press the opposite side of the applicator against the body tissue in the opening. Electrical 30 current is then applied to the microwave antenna 4 in order to generate a microwave field for heating the body tissue opposite to balloon 7, this energy being concentrated by reflector 52. During the heating of the body tissue, water may be circulated via the

cooling ducts 28 to cool the outer surface of the jacket, while the temperature within the body opening is measured by thermocouples 50a, 50b, 50c.

It will thus be seen that the inflation of 5 balloon 7 at the distal end of the applicator displaces the applicator laterally within the body opening, thereby firmly pressing the side thereof through which the microwave radiation is transmitted (namely the side opposite to that occupied by balloon 10 7 and reflector 52) firmly against the body tissue. This fixes the position of the jacket, and thereby of the microwave antenna 4, within the body opening, and also conforms the pressed body tissues to the shape of the jacket at the opposite side of reflector 52.

15 The inflation of balloon 7 also enhances the cooling effect produced by the water circulated through the cooling ducts 28, thereby efficiently cooling the body tissue in direct contact with the applicator. This permits the application of 20 relatively large amounts of heat to relatively remote tissue without undue discomfort to the subject, or heat damage to the adjacent tissue lining the body cavity receiving the applicator.

If, however, it is desired to heat the 25 adjacent tissue lining the body cavity received the applicator, the cooling water would not be circulated through the cooling ducts 28. The described applicator may therefore be used for heating relatively remote tissue, in which case cooling water 30 would be circulated through cooling ducts, or adjacent tissue, e.g., tissue, lining the cavity receiving the applicator, in which case there would be no circulation of cooling fluid through the cooling ducts.

The provision of the thermocouples 50a-50c adjacent to the outer face of the jacket but thermally insulated from the cooling ducts 28, and the provision of the balloon pressing the thermocouples against the body tissue, produce a more precise measurement of the temperature of the body tissue being heated by the applicator. Moreover, by passing the electrical conductors to the thermocouples axially along the outer face of reflector 52 (conductor sections 54a, 10 Fig. 3) and then circumferentially (conductor sections 54b, Fig. 3) to their respective thermocouples 50a-50c, the measurements produced by the thermocouples are substantially insensitive to the heat and electromagnetic field produced by the 15 microwave antenna, thereby further increasing the precision of the temperature measurements of the body tissue.

WHAT IS CLAIMED IS:

1. An applicator for insertion into a body opening for medical treatment or for diagnostic purposes, characterized in that said applicator includes: an elongated jacket for insertion into the body opening; a disposable sleeve received on said jacket; and a balloon integrally formed on said disposable sleeve at one side of said jacket, which balloon is inflatable by a fluid to press the opposite side of the jacket and sleeve laterally against the tissue of the body opening, thereby to fix the position of the jacket within the body opening and to conform the pressed body tissue to the shape of said opposite side of the jacket.

2. The applicator according to Claim 1, wherein said inflatable balloon is carried at the distal end of the disposable sleeve and extends laterally to one side thereof.

3. The applicator according to Claim 2, wherein said balloon is of generally conical configuration when inflated, having a narrow tip at one end where joined to said sleeve and a wide base at the opposite end for engagement with the body tissue at said opposite side of the jacket.

4. The applicator according to Claim 3, further including a tubelet extending externally of said disposable sleeve to said balloon for inflating and deflating same.

5. The applicator according to any one of Claims 1-4, further including a microwave antenna disposed within said jacket, said jacket further including cooling ducts adjacent its outer surface for circulating a cooling fluid therethrough in order to prevent undue heating of the body tissue in direct

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contact therewith, said balloon, when inflated, thereby also effecting efficient cooling of the body tissue in contact with said opposite side of the jacket.

6. The applicator according to Claim 5, wherein said jacket further includes a reflector at said one side for reflecting the microwave energy produced by said microwave antenna through said opposite side, and for concentrating the energy to a selected region of the body tissue at said opposite side of the jacket.

7. The applicator according to Claim 6, wherein said microwave antenna includes an inner electrical conductor, a layer of dielectric thereover, serving as a dielectric loading and an outer electrical conductor in the form of a braid; the outer end of said outer electrical braid being folded back over itself at one end of the antenna and being dielectrically separated from the underlying electrical braid by another dielectric layer, thereby forming a dielectric loaded antenna in which the folded back portion of the electrical braid serves as an RF choke suppressing electromagnetic interference.

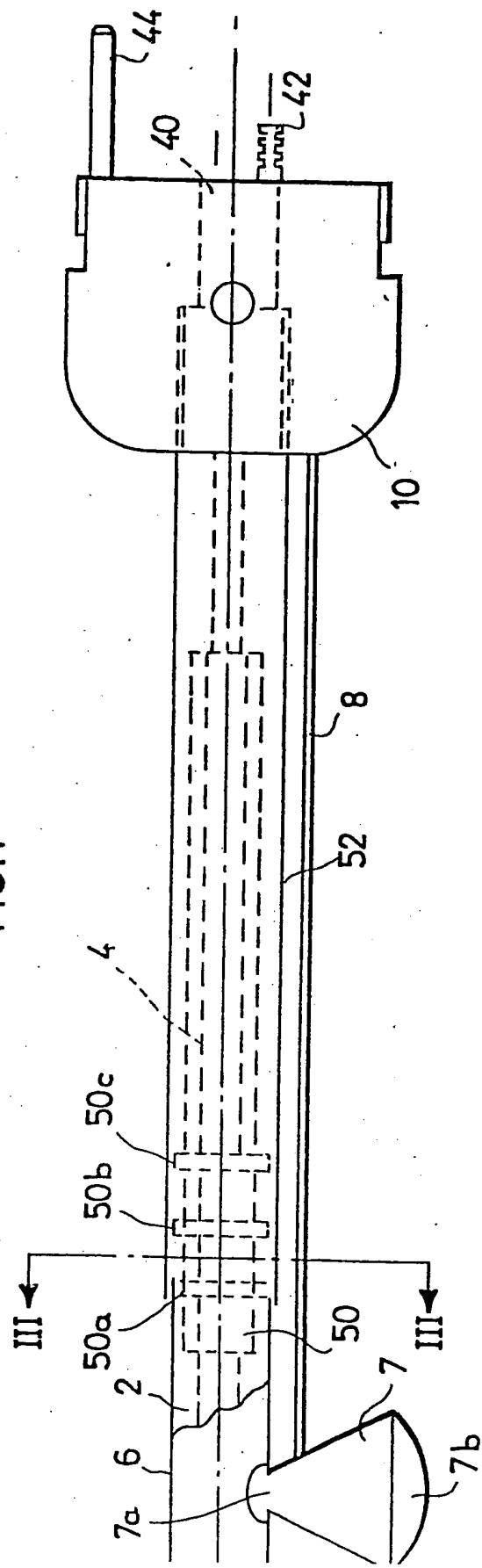
8. The applicator according to any one of Claims 1-7, wherein said jacket further includes a temperature measuring device adjacent to the outer surface of said opposite side of the jacket, said balloon, when inflated, thereby also effecting efficient measurement of the temperature of the body tissue in contact with said opposite side of the jacket.

9. The applicator according to Claim 8, wherein said temperature measuring device includes an electrical conductor having a first section passing

axially of the jacket and reflector along the face of the reflector opposite to that facing the RF heating element so as to be substantially shielded therefrom by the reflector, and a second section passing circumferentially of the jacket from its first section shielded by the reflector to the temperature measuring device.

10. The applicator according to either of Claims 8 or 9, wherein there are a plurality of said temperature measuring devices spaced axially of said jacket, wherein each of said temperature measuring devices being a thermocouple attached to the outer face of the jacket and thermally insulated therefrom.

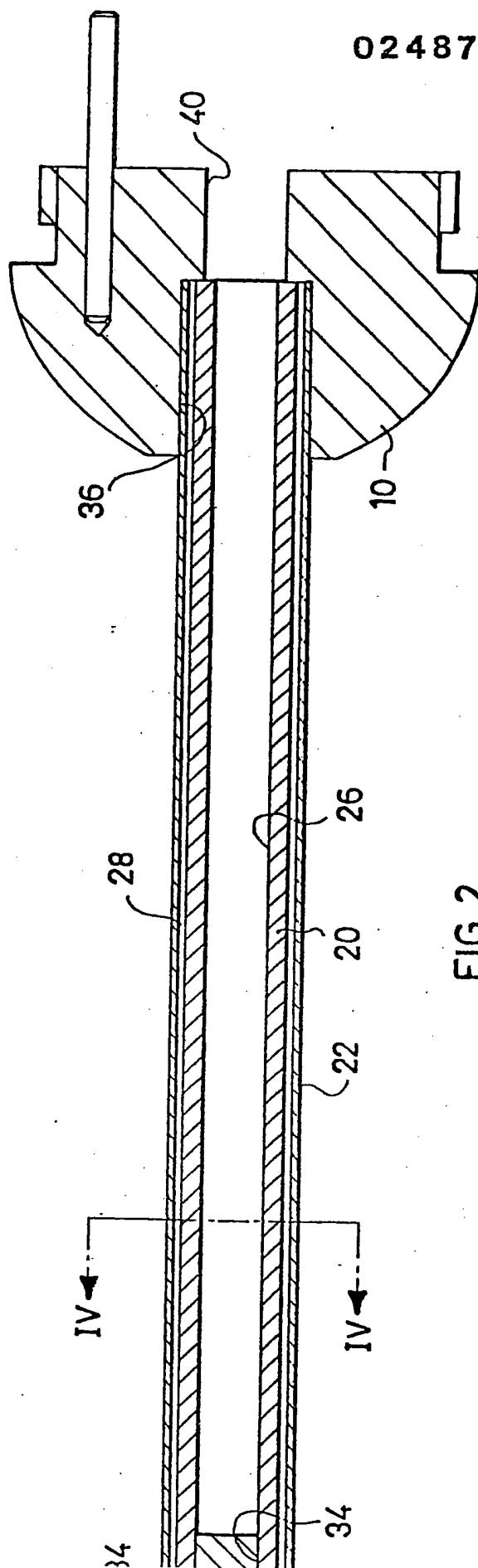
FIG.1



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FIG.2



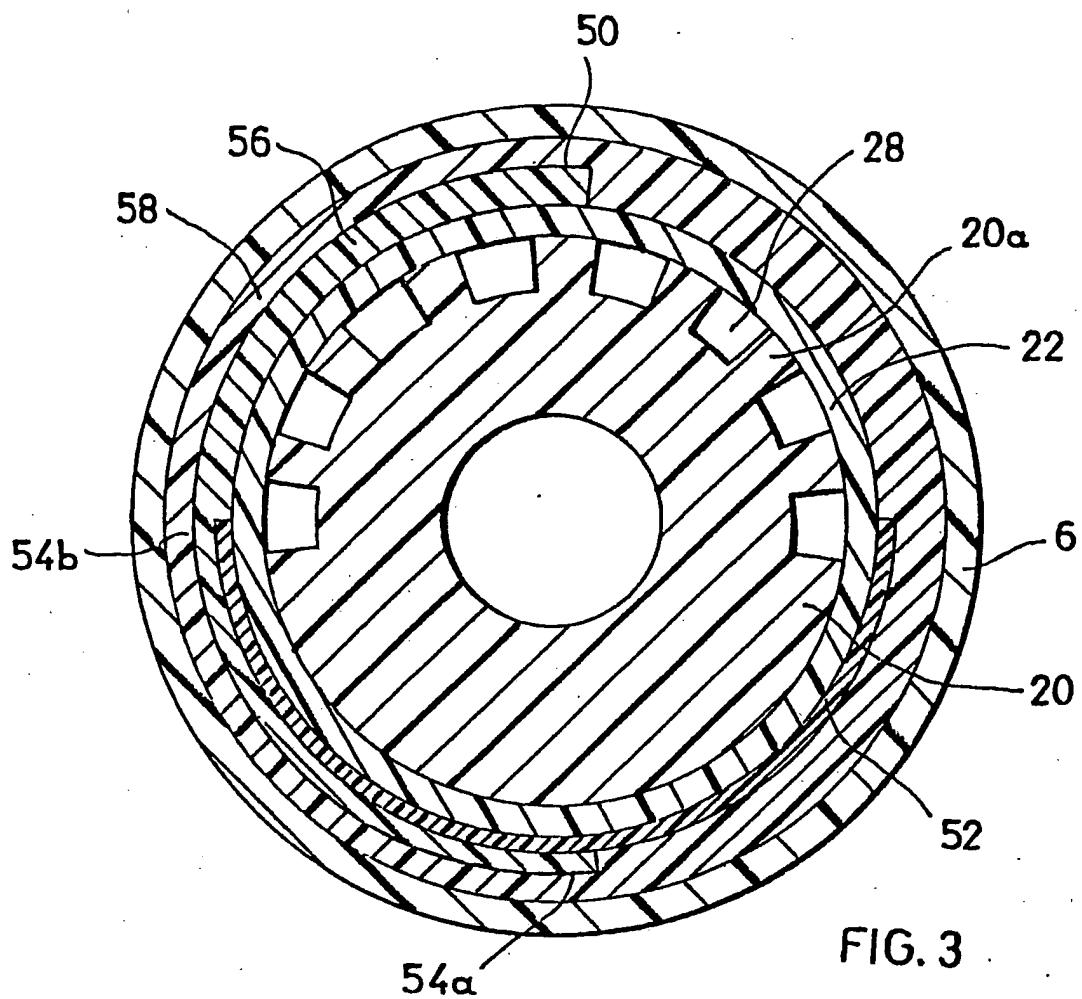


FIG. 3

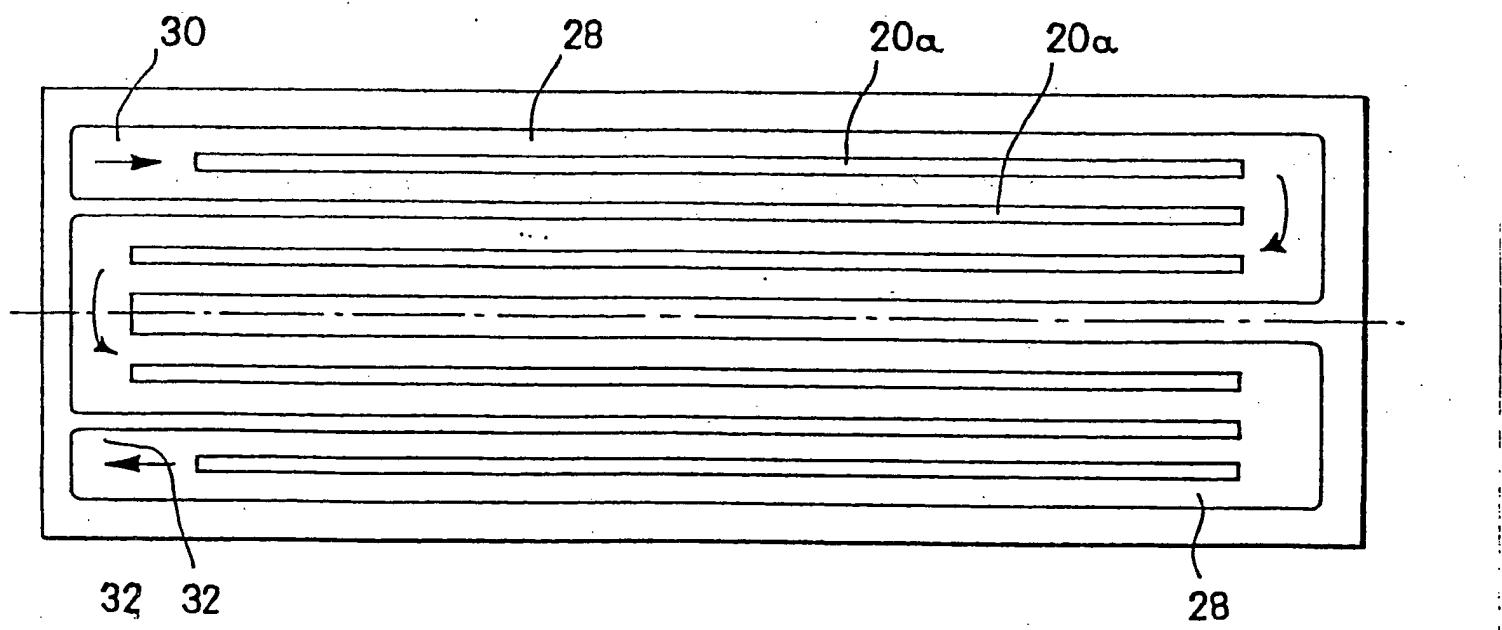


FIG 5

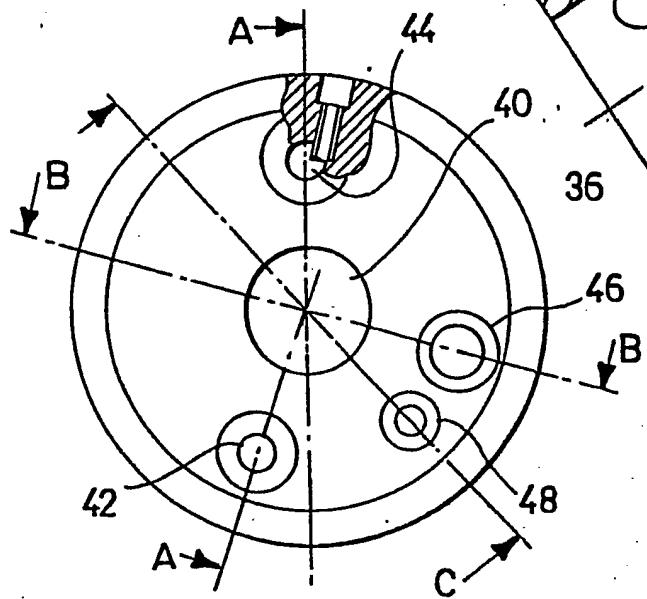


FIG 5c

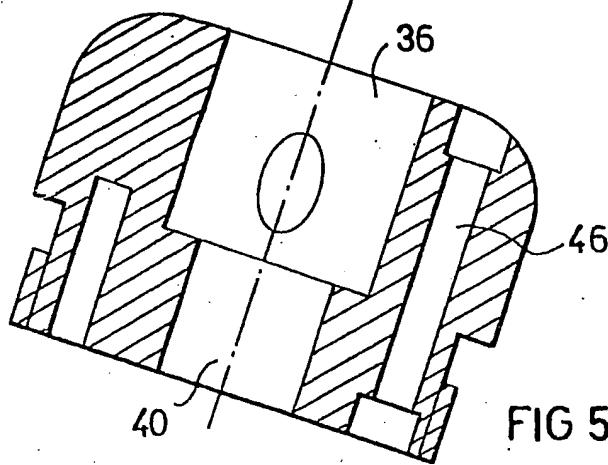
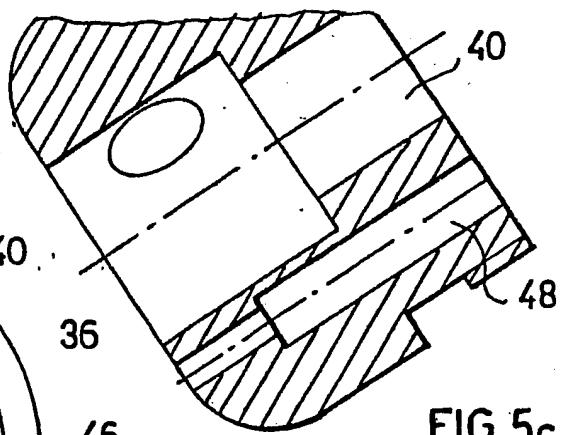


FIG 5b

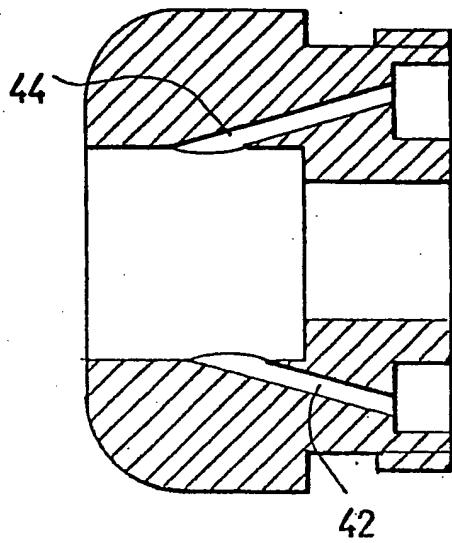
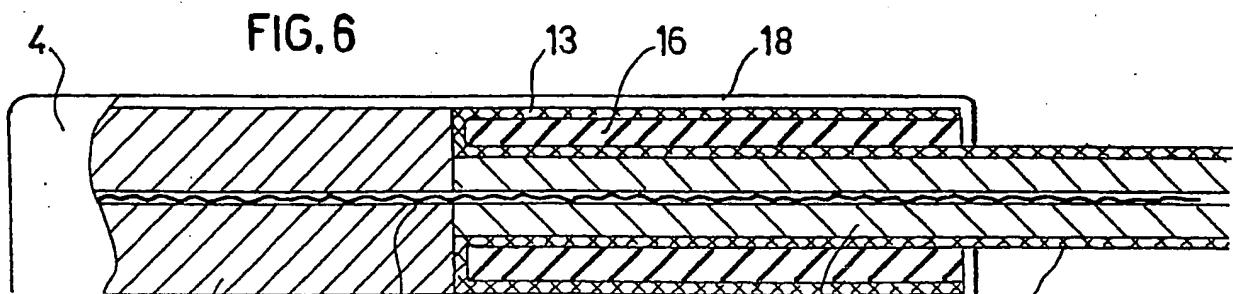


FIG 5a

FIG. 6





EUROPEAN SEARCH REPORT

0248758  
Application number

EP 87630080.7

DOCUMENTS CONSIDERED TO BE RELEVANT			CLASSIFICATION OF THE APPLICATION (Int. Cl.4)
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	
X	<u>EP - A1 - 0 139 607 (YEDA RES. DEV.)</u>	1,2,5, 8	A 61 M 23/00
A	* Totality; especially fig. 6; page 6, line 1 - page 7, paragraph 2; page 9, paragraph 3 - page 10, paragraph 3; page 11, paragraph 2 *	3,4,7, 9,10	A 61 F 7/12 A 61 N 5/04
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A	<u>EP - A1 - 0 105 677 (KUREHA KAGAKU)</u>	1,5	
	* Totality; especially fig. 1,2,5; page 4, paragraph 2 - page 10, paragraph 1; page 14, paragraph 2 - page 17, paragraph 2 *		
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A	<u>WO - A1 - 81/03 616 (BICHER J. et al.)</u>	5	TECHNICAL FIELD SEARCHED (Int. Cl.4)
	* Totality; especially fig. 1,2; page 5, line 12 - page 6, line 37; page 7, lines 30-35 *		A 61 F 7/00 A 61 M 23/00 A 61 M 25/00 A 61 M 29/00
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D,A	<u>US - A - 4 375 220 (F.M. MATVIAS)</u>	5	A 61 N 1/00 A 61 N 5/00
	* Totality; especially fig. 4-9; page 2, line 66 - page 3, line 63 *		
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The present search report has been drawn up for all claims			
Place of search	Date of completion of the search	Examiner	
VIENNA	22-09-1987	LUDWIG	
CATEGORY OF CITED DOCUMENTS			
X : particularly relevant if taken alone	T : theory or principle underlying the invention		
Y : particularly relevant if combined with another document of the same category	E : earlier patent document, but published on, or after the filing date		
A : technological background	D : document cited in the application		
O : non-written disclosure	L : document cited for other reasons		
P : intermediate document	& : member of the same patent family, corresponding document		



European Patent  
Office

## EUROPEAN SEARCH REPORT

**0248758**

Application number

- 2 -

DOCUMENTS CONSIDERED TO BE RELEVANT			EP 87630080.7
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.4)
D,A	<p><u>US - A - 2 032 859 (F.C. WAPPLER)</u></p> <p>* Totality; especially fig. 1,2; page 2, line 38 - page 3, line 21 *</p> <p>--</p>	1,5	
A	<p><u>US - A - 3 811 448 (A.W. MORTON)</u></p> <p>* Fig. 1,2; column 3, lines 1-26, 49-56 *</p> <p>--</p>	1	
A	<p><u>US - A - 3 438 375 (R.E. ERICSON)</u></p> <p>* Fig. 1-3,6,7,17 *</p> <p>--</p>	1	
P,A	<p><u>EP - A1 - 0 204 218 (STÖCKERT INSTR.)</u></p> <p>* Fig. 1; column 2, lines 14-18 *</p> <p>-----</p>		<p>TECHNICAL FIELDS SEARCHED (Int. Cl.4)</p>
The present search report has been drawn up for all claims			
Place of search	Date of completion of the search	Examiner	
VIENNA	22-09-1987	LUDWIG	
CATEGORY OF CITED DOCUMENTS		T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons	
X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category			